

### **Remarks**

Claims 1-25 are pending in the application.

With this amendment, the specification is amended; claims 5 and 6 are amended; and, claims 15-25 are withdrawn from consideration.

Claims 1-14 remain in the application for consideration.

Reconsideration and allowance of the claims as amended in light of the following remarks, are respectfully requested.

### **Election/Restrictions**

According to the Office Action, claims 1-25 stand subject to restriction to one of Group I (claims 1-14) or Group II (claims 15-25).

Responsive to the restriction requirement, Applicants affirm the election to prosecute Group I, claims 1-14, without traverse. Please withdraw claims 15-25.

### **Specification Objections**

The specification is objected to because the abstract should include the features of the movable elongate structures, such as the tines, as well as the method of holding opposing severed urethral tissues together.

In response, the abstract has been amended as set forth above. Applicants request that such amendment be entered. Accordingly, withdrawal of the specification objection is believed proper and respectfully requested.

The specification is also objected to because of the following informality: on page 11, line 16 reads "tines 29" and it should read --tines 33--.

In response, the specification has been amended as set forth above. Applicants request that such amendment be entered. Accordingly, withdrawal of the specification objection is believed proper and respectfully requested.

### **Claim Objections**

Claims 5 and 6 are objected to because in lines 2-3 of both claims recite "a hollow, elongate, flexible catheter body having a proximal end and a distal end" as well as "an inflatable

balloon at the distal end.” Also, in line 5 of both claims, “a drainage lumen” is requested to be changed to --the drainage lumen--.

Applicants amend claims 5 and 6 as set forth above. Applicants request that such amendments be entered. Accordingly, withdrawal of the objection as to claims 5 and 6 is believed proper and respectfully requested.

Claim 6 is also objected to because it reads “inflation means,” “drainage means,” and “tissue approximating means,” which are provided to not be in proper form to invoke 35 U.S.C. 112, 6<sup>th</sup> paragraph.

In response, Applicants first assert that the claim at issue should be claim 9 rather than claim 6, because it is claim 9 and not claim 6 that includes the means plus function language. With regard to claim 9, the objection does not provide enough information with regard to why or what part of the claim is not in proper form, e.g., why the language is not considered to invoke paragraph 6 of section 112. A means and a function are present for the referenced features. Applicants, therefore, request withdrawal of the objection or more information to clarify the objection.

#### **Claim Rejections - 35 USC § 103(a)**

##### **Claims 1-3, 7-10, and 12-14**

Claims 1-3, 7-10, and 12-14 are rejected under 35 USC 103(a) as being unpatentable over Bander (U.S. Patent No. 6,299,598) in view of Seiba (U.S. Publ. No. 20030229364).

Applicants respectfully traverse the rejection. The rejection is untenable because the references cannot be combined to result in all features of the rejected claims. In specific, claims 1-3, 7-10, and 12-14 recite tissue approximating structure on a catheter body, on a proximal side of a balloon. The cited references cannot be combined to result in that feature.

The primary reference, Bander, according to its Abstract, describes a drainage catheter that extends through a percutaneous access site and includes first and second retention balloons for holding the device in place to drain the bladder and for maintaining the patency of the urethra of a patient following a radical prostatectomy. The catheter is held in place by two balloons located along the body of the catheter to maintain patency “during healing of the urethra at [the] anastomotic site.” See column 6, lines 26-28. The

catheter is a “suprapubic catheter,” which is distinguished from a “Foley catheter”: “A suprapubic catheter is preferable to the Foley catheter in that the Foley catheter would be transurethraly positioned and exit the urethra via [the] external urethral orifice.” See, e.g., column 6, lines 29-32. The Bander reference emphasizes the use of a suprapubic catheter over a Foley catheter, e.g.,: “The Foley catheter is undesirable in that the retention balloon can readily permit the flow of urine to the anastomosis site due to the migration of the catheter.” See, e.g., column 6, lines 31-34.

Thus, the Bander reference uses a suprapubic catheter, which places two balloons in the bladder, and a “distal portion” (13) of the catheter positioned in the urethra, and at the site of anastomosis. See Bander figure 4 and the text at column 6, lines 26-28. The “distal portion” (13) of the Bander catheter is placed at the anastomosis site (20) and that distal portion of the catheter is distal from both of the two balloons. See figure 4.

According to the Office action, Bander is said to disclose all the features of the claimed invention except for a tissue approximating structure. The Seiba reference is said to remedy the shortcoming of the Bander reference by describing a tissue approximating structure with multiple, opposing tines on a catheter body.

The rejection fails, though, because, *inter alia*, the combination would not result in tissue approximating structure on a proximal side of a catheter balloon, as claimed. Starting with the primary reference, Bander, the site of anastomosis is distal from both balloons. To place tissue approximating structure at a useful location on the Bander suprapubic catheter, the tissue approximating structure would be required to be distal from the balloons, not on a proximal side of a balloon as claimed. All features of the pending claims are not met; e.g., the feature of tissue approximating structure on a catheter body, on a proximal side of a balloon, is not met. The rejection should be withdrawn.

#### **Claims 4-6, 11, and 14**

Claims 4-6, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bander (U.S. Patent No. 6,299,598) and Seiba (U.S. Publ. No. 20030229364), as applied to claims 1, 3, and 9, and further in view of Biggs et al. (U.S. Patent No. 6,599,311).

As established above, the Bander and Seiba references do cannot be combined to result in all features of the pending claims, including tissue approximating structure on a catheter body, on a proximal side of a balloon.

The Biggs et al. reference fails to remedy this shortcoming of the Bander and Seiba references, and the rejection still fails to show all features of the claims and should be withdrawn.

In view of the present amendments and remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn. Reconsideration of the claims as amended, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

By: D.C. Schulte  
Daniel C. Schulte, Reg. No. 40,160  
**Customer Number 33072**  
Phone: 651-275-9806  
Facsimile: 651-351-2954

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